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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,677

04/19/2007

Robert Gordon Hood

9931-010US

4798

22897 7590 05/27/2008

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EXAMINER

TANNER, JOCELYN C

ART UNIT

PAPER NUMBER

4133

MAIL DATE

DELIVERY MODE

05/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,677	Applicant(s) HOOD ET AL.	
	Examiner JOCELIN C. TANNER	Art Unit 4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/3/2006, 12/4/2006, 3/19/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is in response to the application filed on April 19, 2007 in which claims 1-32 are presented for examination.

Status of Claims

Claims 1-32 are pending, of which 1 is in independent form. Claims 1-32 are rejected under 35 U.S.C. 103(a).

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 8/3/2006, 12/4/2006 and 3/19/2008 were filed before and after the mailing date of the patent application on 4/19/2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 17-25, and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (US PGPub No. 2003/0139807) in view of Falotico et al (US Patent No. 7,195,640).

Regarding claim 1, Houston et al or "Houston" herein, discloses a stent or "drug delivery device" including a vascular implant [0011], i.e. stent, stent graft or graft, having a blood-contacting surface and a helical formation on the blood contacting surface (FIG. 1, element #2), the helical formation being capable of inducing helical flow of blood flowing past [0042]. However, Houston fails to disclose a drug.

Falotico et al, or "Falotico" herein, teaches a coated medical device or "drug delivery device" that may be coated with any number of therapeutic drugs, agents or compounds (column 10, lines 3-5).

Because Houston and Falotico teach known devices, i.e. stents, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the helical stent of Houston with the therapeutic and pharmaceutical drug coating, as taught by Falotico, for the predictable result of effectively maintaining vessel patency with treatment while reducing local turbulence in blood flow and reduced potential toxicity of drugs.

2. Regarding claim 2, the combination of Houston and Falotico discloses all of the limitations. Further, Falotico teaches a stent or "drug delivery device" formed by the mixing of a polymer and rapamycin, an antibiotic used to treat restenosis, by directly incorporating rapamycin into a polymeric matrix wherein the rapamycin elutes from the polymeric matrix over time into the surrounding tissue (column 14, lines 1-4 and column 18, lines 50-59).

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3. Regarding claim 3, the combination of Houston and Falotico discloses all of the limitations. Further, Falotico teaches coating the inner and outer surface of the stent with drug/drug combinations wherein the inner surface contains the helical formation (column 12, lines 53-55).

4. Regarding claim 4, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a helical formation made from polyurethane, a polymer [0039].

5. Regarding claim 17, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a helical formation made from polymer foam [0050].

6. Regarding claim 18, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a helical formation made from polyurethane [0039].

7. Regarding claim 19, the combination of Houston and Falotico discloses all of the limitations. Falotico teaches a drug that is bound onto the cellular structure of the polymer through crosslinking wherein the pharmaceutical agents are bonded to the atoms and chains of the polymers of the coatings and films (column 19, lines 65-67).

8. Regarding claim 20, the combination of Houston and Falotico discloses all of the limitations. Falotico teaches therapeutic and pharmaceutical coatings of antiplatelet

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agents, anticoagulants and fibrinolytic agents (column 10, lines 14, 29-30 and column 18, lines 29-30) wherein the coatings can be layered to control release of different agents placed in different layers (column 18, lines 2-4).

9. Regarding claim 21, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a vascular implant that is a stent, stent graft and a graft [0011].

10. Regarding claim 22, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a membrane or "sleeve" within the stent that is made of flexible material and attached to the body of the stent [0046].

11. Regarding claim 23, the combination of Houston and Falotico discloses all of the limitations. Houston discloses the sleeve being formed of PTFE material [0046].

12. Regarding claims 24 and 25, the combination of Houston and Falotico discloses all of the limitations. Falotico teaches a drug that is releasably associated with the blood-contacting surface of the vascular implant and helical formation wherein the coatings containing therapeutic agents are applied into and onto the stent by way of spraying, spinning or dipping (column 14, lines 29-31) and the drug is released through diffusion dependent on the desired release profile (column 19, lines 29-36).

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13. Regarding claim 27, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a helical formation having at least one fin (FIG. 3, element #6 and #7, [0048]).

14. Regarding claim 28, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a fin having the shape of a right-angle triangle in cross-section (FIG. 5, [0048]).

15. Regarding claim 29, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a fin having the shape of an isosceles triangle in cross-section (FIG. 6, [0049]).

16. Regarding claim 30, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a fin having the shape of a bell in cross-section (FIG. 7).

17. Regarding claim 31, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a fin having the shape of an asymmetric bell in cross-section (FIG.7).

18. Regarding claim 32, the combination of Houston and Falotico discloses all of the limitations. Houston discloses a helical formation having a groove between the two

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extending fins that extend along the length of the longitudinally extending member of the formation (FIGS. 1 and 2).

19. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (US PGPub No. 2003/0139807) in view of Falotico et al (US Patent No. 7,195,640), further in view of Houston et al (EP 1254645A1).

Regarding claim 26, the combination of Houston and Falotico discloses all of the limitations. However, the combination of Houston and Falotico fails to disclose an angle of the helical formation between 8° and 20°.

Houston et al teaches a helical formation having a helix angle between 5° and 50°, preferably about 16°, to reduce turbulence [0013].

Because the combination of Houston and Falotico and Houston et al teach known devices, i.e. helical formations to reduce turbulent flow, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the helical formation of the combination of Houston and Falotico with the helix angle of 16° (between 8° and 20°), as taught by Houston et al, for the predictable result of inducing helical flow to eliminate turbulence.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chudzik et al (US Patent No. 6,344,035), Hossainy (US Patent No. 6,712,845) and Houston et al (US PGPub No. 2003/0120257A1) are related to

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coatings for implantable medical devices to provide release of pharmaceutical agents from surfaces and helical blood flow tubing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
Examiner, Art Unit 4133

5/20/2008

/Frantz Coby/
Supervisory Patent Examiner
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